

# **Consultation with EPA's Science Advisory Board: "Reproducibility" Under the OMB Information Quality Guidelines**

August 27, 2002

## **Introduction**

The White House Office of Management and Budget (OMB) issued *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Dissemination by Federal Agencies*, effective January 3, 2002, in response to section 515 of Public Law 106-554. The OMB guidelines directed each affected agency to develop its own guidelines to ensure and maximize the quality of the information it disseminates to the public. OMB defines the term "quality" to encompass the concepts of "utility, objectivity, and integrity."<sup>1</sup> Further, beyond a basic standard of quality, OMB adds the concept of "reproducibility"<sup>2</sup> for the purpose of establishing a higher standard of quality for information deemed by the agency to be "influential."<sup>3</sup> EPA has developed its final information quality guidelines, to be issued by October 1, 2002, which build upon numerous established agency policies and procedures for ensuring the quality of information.

## **Relevant Aspects of the OMB Information Quality Guidelines**

The OMB guidelines direct that agencies adopt a basic standard of quality as a performance goal for information disseminated by the agency. Information quality (including objectivity, utility, and integrity) is to be ensured and established at levels appropriate to the nature and timeliness of the information to be disseminated. As a general matter, the OMB guidelines regard scientific and technical information that has been subjected to formal, independent, external peer review (e.g., the review process used by scientific journals) as presumptively objective, although the presumption is rebuttable. The OMB guidelines, however, recognize limits in the effectiveness of journal peer review as a quality-control mechanism, and outline additional quality checks beyond peer review for the dissemination of influential information that will likely have an important public policy or private sector impact. The OMB guidelines take the position that the more important the information, the higher the quality standards to which it should be held. However, the OMB guidelines also recognize that information quality comes at a cost, and that agencies should weigh the costs and benefits of

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<sup>1</sup> According to OMB's guidelines, "utility" refers to the usefulness of information to its intended users. "Objectivity" involves two distinct elements, presentation and substance, such that objectivity involves the presentation of information in an accurate, clear, complete, and unbiased manner, as well as ensuring that the substance of the information is accurate, reliable, and unbiased. "Integrity" refers to the security of the information.

<sup>2</sup> According to OMB's guidelines, "reproducibility" means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (less) important impacts, the degree of imprecision that is tolerated is reduced (increased).

<sup>3</sup> According to OMB's guidelines, "influential" scientific, financial, or statistical information refers to disseminated information that an agency can reasonably determine will have or does have a clear and substantial impact on important public policies or important private sector decisions.

higher information quality in determining the level of quality to which disseminated information will be held.

For influential scientific, financial, or statistical information, the OMB guidelines generally require a high degree of transparency<sup>4</sup> about data and methods to facilitate the reproducibility or independent reanalysis of such information by qualified third parties. The concept of reproducibility in OMB's guidelines applies to two categories of influential information: (1) original and supporting data and (2) analytic results.

With regard to influential original and supporting data, the OMB guidelines urge caution in that "it may often be impractical or even impermissible or unethical to apply a reproducibility standard" to such information. The OMB guidelines further specify that:

"... agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement. Agencies may identify, *in consultation with the relevant scientific and technical communities*, those particular types of data that can practically be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints." [emphasis added]

Although not defined in the OMB guidelines, EPA considers the term "original and supporting data" to be broadly inclusive of all original measurements, observations, determinations, and other representations of fact made and presumably recorded in the course of scientific, financial, or statistical work, as well as all supporting measurements, observations, determinations, and other representations of fact collected from or provided by other sources. Examples of such scientific data disseminated by EPA include measurements of environmental conditions and emissions into the environment, data generated during the conduct of laboratory and field experiments (including studies of physical, chemical, physiological, and toxicological properties), chemical and physical analyses and related calibration and quality control measures, and demographic and public health statistical information.

With regard to influential analytic results, the OMB guidelines do not intend that each analytic result be reproduced, but rather that the information be transparent as to how analytic results are generated. In particular, disseminated analytic results are to be clear about the specific data used, the various assumptions employed, the specific analytic methods applied, and the statistical procedures employed. Examples of analytic results disseminated by EPA include results from environmental models; statistical results from laboratory animal, human clinical, and epidemiological studies; exposure analyses and human health and ecological risk assessments; and regulatory impact analyses and cost-benefit assessments.

The guidelines note that making underlying data and analytic methods and models publicly available facilitates the reproducibility of analytic results. However, the guidelines acknowledge that this approach "does not override other compelling interests such as privacy,

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<sup>4</sup> Although not defined in the OMB guidelines, "transparency" generally refers to the clarity and completeness with which data and methods of analysis are documented, such that replication is possible if information is sufficiently transparent.

trade secrets, intellectual property, and other confidentiality protections.” To address situations where public access to data and methods cannot practically occur due to other compelling interests, the OMB guidelines specify that agencies shall perform especially rigorous “robustness checks” to analytic results and document what checks were undertaken. Although not defined in the OMB guidelines, “robustness checks” are understood to refer, for example, to assessments of the sensitivity of analytic results to assumptions and choices of analytic methods that have been employed, and to evaluations of analytic results in the context of integrative assessments of an entire body of related scientific and technical information. The rigor of robustness checks is to be appropriate to the importance of the information involved, although in all cases specific data sources and quantitative methods and assumptions are to be identified. The appropriate degree of rigor in robustness checks is left to the discretion of the agency and *the relevant scientific and technical communities that work with the agency*.

In considering analytic results derived, for example, from an epidemiological study, varying degrees of robustness checks might be undertaken. For example, the robustness of the results might be evaluated by considering the extent to which various alternative model specifications were employed or various types of sensitivity analyses were conducted as part of the study or in other similar studies. Robustness might also be considered through comparison of results from one study with results from other studies, conducted in the same or other locations, using the same or different approaches (e.g., statistical methods, assumptions, study populations). The OMB guidelines note that even when confidentiality protections apply, as in the case cited by OMB of epidemiological studies of particulate air pollution, it could still be feasible to reproduce results by extending the confidentiality protections to a qualified third party to replicate the originally reported results.

### **Charge to the Science Advisory Board**

- < EPA requests that the SAB Executive Committee reflect upon and describe in general terms the commonly accepted means by which the scientific community (e.g. researchers in the physical, natural and other sciences) communicate information, analysis and findings such that it can be reproduced by peers; considering as well approaches to determining the robustness of analytic results in the absence of actual data due to various constraints (e.g. confidentiality).
- < We also ask for the SAB’s views as to the potential usefulness of further consultation on these issues. To the extent that further consultation may be useful, we ask for the SAB’s views on approaches and supporting information that could be used to structure any future consultation on these issues, so as to elicit input that further informs the Agency’s implementation of our guidelines relative to the issue of reproducibility.

This consultation with the SAB is intended to focus on one key element of EPA’s guidelines, reproducibility. This is consistent with the OMB guideline that identifies specific aspects of reproducibility for consultation with the relevant scientific and technical communities. EPA has elected to consult with the SAB as representative of the scientific and technical communities. EPA’s current draft guidelines reflect EPA’s intentions to ensure reproducibility of disseminated data according to “commonly accepted scientific, financial, or statistical

standards,” and to apply the Agency’s existing quality system and related policies and procedures<sup>5</sup> to the extent practicable in implementing its guidelines. EPA’s draft guidelines also note that SAB consultation is intended to allow EPA to refine our application of existing policies and procedures in addressing the issue of reproducibility, perhaps incorporating such refinements into future revisions of the guidelines.

Thus, through this initial consultation, EPA is interested in ascertaining in general how the academic and scientific community addresses the “reproducibility” of information (i.e., original and supporting data and analytic studies) in the conduct and publication of scientific research. We anticipate that such general input will allow us to better understand the approaches to the reproducibility of research that are commonly accepted in the academic and scientific community. Based on this initial consultation, EPA may seek additional input from the SAB on these issues in the future. To that end, as part of this consultation, we are interested in the SAB’s views as to the potential usefulness of further consultation and approaches that could be used to structure any future consultation on these issues.

To put the charge to the SAB into perspective, we are providing as background information the final OMB Information Quality Guidelines (January 2, 2002) and the proposed EPA Information Quality Guidelines (May 1, 2002).

### **Considerations Identified for This Consultation**

We believe that SAB’s consideration of the following issues and questions can help to provide a more specific framework for this consultation.

1. OMB is interested in characterizing general “types” of original and supporting data that can practicably be expected to be reproducible given ethical, feasibility, or confidentiality constraints. To what extent can this issue be addressed in the general sense, and to what extent do case-specific considerations (e.g., relative importance and uniqueness of the data within a field of study; contractual arrangements under which the data were generated) necessarily come into play in addressing this issue?
  - < What does the scientific community consider to be a reasonable level of data provision, summary statistics, or model parameter specification necessary to facilitate replication of data in peer reviewed literature for various types of data?
  - < How does the level of data expected to be provided with a paper submitted for review vary with the importance or uniqueness of the study findings?
  - < To what extent can and do peer reviewers request and obtain data during their review of a submitted paper?
  - < What constraints might there be on researchers to make publicly available various types of data (before or after publication), and what would be the impact on the researcher of making their data publicly available?

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<sup>5</sup> EPA’s Quality System and related policies and procedures are summarized and referenced in EPA’s draft guidelines.

- < What stipulations are or might appropriately be placed on access to and use of such data?
2. Similarly, OMB is interested in characterizing general classes or types of analytic results for which compelling interests, such as privacy, trade secrets, intellectual property, and other confidentiality protections, would limit the public availability of the underlying data or methods. To what extent can this issue be addressed in the general sense, and to what extent do case-specific considerations (e.g., relative importance and uniqueness of the study results within a field of study; contractual arrangements under which the study was conducted) necessarily come into play in addressing this issue?
    - < What options are currently available for gaining access to and reproducing underlying data and analyses within the scientific community that might otherwise be limited by such protections?
    - < What alternative approaches might be considered for the future to facilitate the availability of underlying data and methods when these types of protections apply?
  3. What approaches to conducting “robustness checks” of analytic results would the scientific and technical community consider appropriate for various types of analytic results with varying degrees of importance?
    - < What types of robustness checks are typically applied in the scientific and technical community to assess published analytic results?
    - < How might robustness checks be made to be especially rigorous when applied to influential scientific, financial, or statistical information?

We recognize the difficulties inherent in attempting to address these general issues and questions in the abstract. Thus, SAB may find it helpful to address the issues and questions outlined above by considering a range of examples of types of original data and analytic studies from peer-reviewed publications that EPA commonly considers. EPA offers the following examples as a starting point for the SAB’s consideration:

- < Examples of *original data* could include: air/groundwater/solid waste monitoring data; personal exposure monitoring for ambient pollutants; and data on chemical releases from facilities.
- < Examples of *analytic studies* could include: analysis of epidemiological studies of long-term population exposures to pollutants; simulation studies of environmental conditions using multi-media models; and regulatory economic impact analyses.